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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,486	08/17/2001	Geert Jannes	,2551-59	4000

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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,486

Applicant(s)

JANNES ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-114 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,55,69,82,83,86,89,93,103,109,113 and 114 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/765,332.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 (2 pages) 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 56-68,70-81,84,85,87,88,90-92,94-102,104-108 and 110-112.

1. Applicant's election with traverse of Group I, SEQ ID NO:111, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that "a search of all the claimed subject matter is not believed to present an undue burden on the Examiner", and that the instant restriction requirement is not consistent with the restriction requirement issued in the grandparent '332 application. This is not found persuasive for the following reasons. Firstly, search burden with respect to nucleic acid sequences depends upon several factors, including length of sequences and number of sequences, and is subject to Group 1600 policy, and thus is not entirely at the discretion of the examiner. In the instant case, examination of over 70 nucleic acid sequences of approximately 500 bases in length would clearly provide a search burden on the examiner and the Office. Any further discussion of this matter should be directed to one of the Technology Center 1600 Biotech Practice Specialists. Secondly, since the previously-examined claims involved much smaller oligonucleotides, it is not believed that any comparisons made between the number of sequences examined in prior prosecution and those proposed in the instant requirement is valid. Also, given the difference in subject matter prosecuted previously, it is not agreed that the instant requirement is inconsistent with those previously given, or that another modified restriction requirement should be issued. However, the request on page 10 of the response that at least SEQ ID NO: 111-115, drawn to Pseudomonas sequences, be examined, has been considered and granted.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 56-68, 70-81, 84, 85, 87, 88, 90-92, 94-102, 104-108, and 110-112 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Also claims 54, 55, 82, 83, 86, 93, 113, and 114, insofar as they contain or refer to sequences other than SEQ ID NO:111-115, contain nonelected subject matter. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The instant claims relate to 16S-23S rRNA spacer sequences from Pseudomonas species.

4. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;**
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

5. It is noted that SEQ ID NO:111-115 have support in priority document EPO 95 870 032.0, and accordingly the examined subject matter receives benefit of the filing date of 04/07/95.

6. Claim 55 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 55 is drawn to the exact same sequences (SEQ ID NO:111-115) as claim 54. Describing these sequences as "respiratory tract microorganism-specific" in claim 55 fails to change the scope of the claim.

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 54, 55, 69, and 89 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (product of nature). Due to the open language of the claims (nucleic acid sequence comprising a 16S-23S rRNA spacer sequence), said claims read on naturally-occurring nucleic acid from the various *Pseudomonas* species (i.e., the native bacterial chromosome or total genomic DNA,

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which clearly "comprises" the recited sequences). Amending the claims to require that the recited nucleic acids be "isolated" would obviate this rejection.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 54, 55, and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen (US 4,508,823).

These claims are drawn to nucleic acids comprising a sequence including that of SEQ ID NO:111, which is the 16S-23S rRNA spacer sequence from *Pseudomonas aeruginosa*. Due to the open claim language, the claims encompass any larger nucleic acid which comprises said sequence.

Olsen discloses isolated chromosomal DNA from *Pseudomonas aeruginosa*, which inherently comprises the sequence of SEQ ID NO:111 (see column 6, lines 3-59). This rejection would be obviated by amending the claims to require nucleic acids "consisting of" the recited spacer sequences.

10. Claims 54, 55, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Atlas et al. (US 5,298,392).

These claims are drawn to nucleic acids comprising a sequence including that of SEQ ID NO:115, which is the 16S-23S rRNA spacer sequence from *Pseudomonas putida*. Due to the open claim language, the claims encompass any larger nucleic acid which comprises said sequence.

Atlas et al. disclose isolated genomic DNA from *Pseudomonas putida*, which inherently comprises the sequence of SEQ ID NO:115 (see column 16, lines 12-16). This rejection would be obviated by amending the claims to require nucleic acids "consisting of" the recited spacer sequences.

11. Claim 82 is rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al. (US 5,358,846), as well as under 35 U.S.C. 102(e) as being anticipated by Molin et al. (US 5,545,541).

This claim is drawn to a method of detecting nucleic acids comprising a sequence including that of SEQ ID NO:111 or 115, which is the 16S-23S rRNA spacer sequence from *Pseudomonas aeruginosa* or *putida*, respectively. Due to the open claim language, the claims encompass detection of any larger nucleic acid which comprises said sequences.

Ohno et al. disclose detection of *Pseudomonas aeruginosa* DNA, which inherently comprises the sequence of SEQ ID NO:111, using a DNA probe (see column 6, lines 51-52).

Molin et al. disclose detection of *Pseudomonas putida* DNA, which inherently comprises the sequence of SEQ ID NO:115, using a DNA probe (see column 38, line 60 to column 39, line 4).

These rejections would be obviated by amending the claims to require detection of nucleic acids "consisting of" the recited spacer sequences.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 83, 86, 93, 103, 109, 113, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Ohno et al. or Molin et al.

Claims 83 and 86 are drawn to the method of claim 82 as rejected above, with further limitations regarding the well known and commonly used techniques of

sequence analysis and taxon-specific probe use. Claims 93, 103, 109, 113, and 114 are drawn to similar methods, differing only in that detection is in a respiratory tract sample.

Ohno et al. and Molin et al. disclose detection of nucleic acids from the important human pathogens *P. aeruginosa* and *P. putida*, but not the further claim limitations.

One of ordinary skill in the art would have been motivated to further apply the well known and commonly used techniques of sequence analysis and taxon-specific probes in the detection methods of Ohno et al. or Molin et al. because such techniques would have provided further valuable information, such as strain differences, mutations, etc. Further, one of ordinary skill in the art would have been motivated to apply the methods of Ohno et al. or Molina et al. to any type of bodily sample known or suspected of harboring these pathogenic organisms, because it clearly would have been obvious to look for such organisms where they would be expected to occur. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods. As noted above, this rejection would be obviated by amending the claims to require detection of nucleic acids "consisting of" the recited spacer sequences.


13. ALLOWABLE SUBJECT MATTER: the particular spacer sequences of SEQ ID NO:111-115 are considered to be allowable subject matter, as no prior art has been found teaching or suggesting these sequences. None of the current claims are free of the prior art.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

March 4, 2003